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41838	7590 08/24/2005		EXAMINER		
GENERAL ELECTRIC COMPANY (PCPI)			SULLIVAN, JULIANNE M		
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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/064,749	DARROW ET AL.				
Office Action Summary	Examiner	Art Unit				
	Julianne M. Sullivan	3737				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>27 May 2005</u> .						
3) Since this application is in condition for allowar	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4) Claim(s) 1≥17 and 19-30 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 1-17 and 19-30 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examine 10) The drawing(s) filed on 13 August 2002 is/are: Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the original	a)⊠ accepted or b)⊡ objected drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
Attachment(s)						
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) 	4) Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date		Patent Application (PTO-152)				

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DETAILED ACTION

Response to Arguments

- 1. Applicants' arguments with respect to claims 1-17 and 19-30 have been considered but are most in view of the new ground(s) of rejection.
- 2. With respect to Applicants' arguments regarding the rejection of Claims 1, 7-9, 13-15, 23 and 27 under the judicially created doctrine of obviousness-type double patenting over Claims 1, 3, 14, 16 and 17 of U.S. Patent No. 5,211,165 to Dumoulin et al., the Examiner has modified the rejection as a result of Applicants' amendment to reflect that the above-identified claims are now rejected over Dumoulin et al. '165 in view of Dumoulin et al. (U.S. Patent No. 5,251,635). Dumoulin et al. '635, as discussed in the previous action and further discussed below, teaches the elements newly added to the independent claims. In addition, the remaining double patenting rejections of the dependent claims are maintained.
- 3. With respect to Applicants' arguments regarding the rejection of Claims 1-9, 13-15, 17, 19, 22-25 and 27 as anticipated by Dumoulin et al. '165, the Examiner has modified the rejection as a result of Applicants' amendment. The claims are now rejected as unpatentable over Dumoulin et al. '165 in view of Dumoulin et al. '635.
- 4. With respect to Applicants' arguments regarding the rejection of Claims 1-10, 13-19 and 22-30 as anticipated by Dumoulin et al. '635, Applicants' attention is directed to Dumoulin et al. '635 at column 7, lines 38-43. There, the Dumoulin et al. '635 reference teaches that the operator initiates image acquisition at a selected location through an interface that is adapted to respond to the operator's input. The Examiner has interpreted the initiation of acquisition of an image at selected coordinates as meeting the claimed limitations of a target region of interest

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within the subject selected by an operator from an image. Additionally, the interface of Dumoulin et al. '635 by which the operator initiates acquisition is adapted to respond to that operator input, which is an input of coordinates marking the target region in that the images are acquired at a specified position and orientation. Further, the interface is capable of being adapted to other types of user input. Therefore, Dumoulin et al. anticipates the amended claims of the present application and the rejection is maintained.

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5. In response to Applicants' argument that the references fail to show certain features of Applicants' invention, it is noted that the features upon which Applicants rely (i.e., positioning of the medical device within the target region of interest without moving the subject) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Objections

6. Claim 13 is objected to because of the following informalities: there is insufficient antecedent basis for the limitation "the medical imaging device" in line 8. Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-10, 13-17, 19 and 22-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1, 3, 14, 16 and 17 of U.S. Patent No. 5,211,165 to Dumoulin et al. in view of Dumoulin et al. (U.S. Patent No. 5,251,635). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same tracking and positioning system for medical devices used within the body.

Regarding Claims 1, 7-9, 13-15, 23 and 27 of the present application, Dumoulin et al. '165 claims all of the features of the present invention, including a medical device adapted for internal use (Claim 1, col. 7, line 50), an imaging device (Claim 1, col. 7, lines 63-65), and a medical device monitoring subsystem that monitors the position of the device and provides feedback when the device leaves the region of interest (Claim 1, col. 7, lines 59-62 and 66-68 and col. 8, lines 1-5). Dumoulin et al. '165 further claims an imaging system that may be an X-ray imaging system (Claim 14, col. 9, lines 35-37), an MRI system (Claim 16, col. 10, lines 1-3)

or a PET system (Claim 17, col. 10, lines 4-6), an invasive device that may be a guide wire, a catheter, an endoscope, a laparoscope or a biopsy needle (Claim 3, col. 8, lines 32-35), a tracking device for tracking the location of the medical device (Claim 1, col. 7, lines 51-62), and a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images and the processor is further adapted to monitor a position of the medical device relative to the region of interest (Claim 1, col. 7, lines 66-68 and col. 8, lines 1-5), except for explicitly stating that the target region of interest is selected by an operator from an image or that the interface responds to operator input of coordinates of the desired target position of the medical device. In the same field of endeavor, Dumoulin et al. '635 teaches that the operator initiates image acquisition at a selected location through an interface that is adapted to respond to the operator's input (col. 7, lines 38-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine this feature of the '635 patent with those of the '165 patent in order to provide imaging or therapy at the appropriate location and in order to provide improved placement of the device.

Regarding Claims 2-4, 22 and 25, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except for expressly stating that the monitoring subsystem receives configuration information corresponding to the medical device comprising at least one of three-dimensional coordinates of the device, tracking method information, physical dimensions of the device and a model representation of the device, that the monitoring subsystem is responsive to movement of the subject or of the medical device relative to the target region and that the subsystem has a predetermined response of at least one of terminating the

therapy, activating the imaging system to acquire a new image and activating an advisory message. In the same field of endeavor, Dumoulin et al. '635 teaches all of the above limitations. The '635 patent teaches that the monitoring subsystem receives configuration information corresponding to the medical device that is tracking method information (col. 4, line 68 and col. 5, line 1), that the monitoring subsystem is responsive to movement of the medical device relative to the target region (col. 7, lines 24-37) and that the subsystem has a predetermined response of activating the imaging system to acquire a new image (col. 7, lines 31-39). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the features of the monitoring subsystem of Dumoulin et al. '635 with the monitoring subsystem of Dumoulin et al. '165 in order to allow the operator to choose the tracking method used and to provide new images when the device has moved without requiring additional operator action (see for motivation Dumoulin et al. '165 at col. 7, lines 29-32).

Regarding Claims 5, 6, 17, 19 and 24, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except for expressly stating that the subsystem provides advisory feedback to the interface unit and that the advisory feedback is at least one of a visual icon representing the position of the device, a text message and an advisory. In the same field of endeavor, Dumoulin et al. '635 teaches that the subsystem provides advisory feedback to the interface unit (col. 3, lines 1-4, col. 4, lines 42-46 and col. 7, lines 31-39) and that the advisory feedback is a visual icon representing the position of the device (col. 3, lines 22-25 and col. 4, lines 19-21 and 25-35). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the feedback of Dumoulin et al. '635 in the system of the '165 patent in order to allow the operator to track the location of the device.

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Regarding Claims 10, 16, 26 and 28-30, Dumoulin et al. '165 claims all of the features of the present invention, as discussed above, except that there is a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device and that the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest. In the same field of endeavor, Dumoulin et al. '635 teaches a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these features of the '635 patent with those of the '165 patent in order to provide imaging or therapy at the appropriate location and in order to provide improved placement of the device.

9. Claims 2, 11, 12, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 5,211,165 to Dumoulin et al. in view of Dumoulin et al. '635 as applied to Claims 1, 13 and 23 above, and further in view of Panescu et al. (U.S. Patent No. 5,916,163).

Dumoulin et al. '165 in view of Dumoulin et al. '635 claims all of the features of the present invention, as discussed above, except for expressly stating that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images

acquired, and where the visual representation is a wire-frame model of the device. In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '165 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 11. Claims 1-10, 13-17, 19 and 22-30 rejected under 35 U.S.C. 102(b) as being anticipated by Dumoulin et al. (U.S. Patent No. 5,251,635).

Regarding Claims 1, 7, 13 and 23, Dumoulin et al. '635 teaches a medical device positioning system and method including a medical device adapted for internal use for performing the medical procedure, an imaging device, a medical device monitoring subsystem for monitoring the position of the medical device relative to a target region of interest within the

subject and for providing feedback to an interface unit when the position of the medical device deviates from the target region of interest, a tracking device, a processor coupled to the medical imaging device and the tracking device for generating images of the region of interest with a visual representation of the medical device superimposed on the images, where the processor is further adapted to monitor a position of the medical device relative to the region of interest and to respond to changes in the position and provide feedback to an interface and where the operator initiates image acquisition at a selected location through an interface which is adapted to respond to the operator's input (col. 1, lines 60-63, col. 2, lines 2-10, 61-66 and 68 and col. 3, lines 1-4, 12-16 and 35-39, col. 4, lines 16-19 and col. 7, lines 24-43).

Regarding Claims 2-6, 17, 19, 22, 24 and 25, Dumoulin et al. '635 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device, that is responsive to the movement of the medical device relative to the target region within the subject or to movement of the medical device by activating the imaging system to acquire a new image, that provides advisory feedback to the interface unit when the medical device deviates from a target position, where the advisory feedback is a visual icon representing the position of the device (col. 3, lines 1-4 and 22-25, col. 4, lines 19-21, 25-35, 42-46 and 68, col. 5, line 1 and col. 7, lines 24-39).

Regarding Claims 8-10, 14-16 and 26-30, Dumoulin et al. '635 teaches an imaging device that may be an MRI scanner, an X-ray device, a PET system, an ultrasound scanner or any other similar medical diagnostic imaging device, an invasive device that may be at least one of a biopsy needle guide, an invasive probe, an ablation device, a laparoscope and a therapeutic laser, an interface where the operator selects the desired position of the device and a coupling

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between the interface and the processor for displaying the images representing the region of interest and the medical device where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 1, lines 60-63, col. 2, lines 25-28, col. 3, lines 1-4, col. 4, lines 22-48, col. 7, lines 31-43 and 61-68 and col. 8, lines 1-3).

Claim Rejections - 35 USC § 103

- 12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 13. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Panescu et al. (U.S. Patent No. 5,916,163).

Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in

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combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '635 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

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14. Claims 6, 17 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '635 in view of Twiss et al. (U.S. Patent No. 5,375,596).

Dumoulin et al. '635 teaches all of the features of the present invention except for expressly providing that the advisory feedback may be an audible advisory. In the same field of endeavor, Twiss et al. teaches a method and apparatus for locating catheters or other devices within biological tissue where an audible tone is used to indicate proximity to the desired location (col. 7, lines 1-4 and 23-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the audible advisory of Twiss et al. in the system of Dumoulin et al. '635 so that the operator receives location information without the necessity of his looking away from the patient to a display screen.

15. Claims 1-10, 13-17, 19 and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. (U.S. Patent No. 5,211,165) in view of Dumoulin et al. '635.

Regarding Claims 1, 7, 10, 13, 23 and 26, Dumoulin et al. '165 teaches a medical device positioning system and a method for positioning a device comprising an internal medical device, an imaging device, a medical device monitoring subsystem that monitors the position of the

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device and provides feedback to an interface, a tracking device, and a processor coupled to the medical imaging device and tracking device for generating images (col. 2, lines 46-51, 53-57 and 61-65, col. 3, lines 23-27, col. 4, lines 4-7 and col. 7, lines 18-32). Dumoulin et al. '165 does not explicitly teach that the target region of interest is selected by an operator from an image or that the interface responds to operator input of coordinates of the desired target position of the medical device. In the same field of endeavor, Dumoulin et al. '635 teaches that the operator initiates image acquisition at a selected location through an interface that is adapted to respond to the operator's input (col. 7, lines 38-43). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine this feature of the '635 patent with those of the '165 patent in order to provide imaging or therapy at the appropriate location and in order to provide improved placement of the device.

Regarding Claims 2-6, 17, 19, 22, 24 and 25, Dumoulin et al. '165 teaches a monitoring subsystem that is adapted to receive configuration information that is tracking method information corresponding to the medical device, that is responsive to the movement of the medical device relative to the target region within the subject, that responds to movement of the medical device by activating the imaging system to acquire a new image and that provides advisory feedback where the feedback is a visual icon representing the location of the device (col. 2, lines 54-57, col. 3, lines 9-12, col. 4, lines 8-10, 14-24, 31-36 and 58-60 and col. 7, lines 26-32).

Regarding Claims 8, 9, 14, 15 and 27, Dumoulin et al. '165 teaches that the imaging device may be an MRI scanner, an X-ray device, a PET system or an ultrasound scanner and that

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the invasive device may be a guide wire, laparoscope, catheter, biopsy needle or other invasive devices (col. 1, lines 25-26 and 50, col. 7, lines 33-38).

Regarding Claims 16 and 28-30, Dumoulin et al. '165 teaches all of the features of the present invention except for expressly stating that there is a coupling between the interface and the processor that allows display of images and response to movement in real time and that the feedback may be used to navigate the device. In the same field of endeavor, Dumoulin et al. '635 teaches a coupling between the interface and the processor for displaying the images representing the region of interest and the medical device (col. 3, lines 1-4), where the interface is used for positioning the medical device and responding to movement of the medical device in real time, such that the feedback provided to the interface can be used to navigate the device to a region of interest (col. 2, lines 25-28 and col. 7, lines 31-39 and 61-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the real-time response of Dumoulin et al. '635 in the system of Dumoulin et al. '165 in order to provide improved placement of the device. When inserting an invasive device into the body, both the ultimate location as well as the path the device takes to reach that location are critical in order to avoid unnecessary damage to tissues, therefore it would be obvious to use a system that provides a more accurate and contemporaneous location for the device.

16. Claims 2, 11, 12, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumoulin et al. '165 in view of Dumoulin et al. '635 as applied to Claims 1, 13 and 23 above, and further in view of Panescu et al.

Dumoulin et al. '165 in view of Dumoulin et al. '635 teaches all of the features of the present invention except that the monitoring subsystem receives configuration information about

the device that is a model representation, where that information corresponds to a visual representation of the device for superimposing on the images acquired, and where the visual representation is a wire-frame model of the device.

In the same field of endeavor, Panescu et al. teaches a system for locating and positioning a catheter within a body where configuration information about the device is entered into the processing system (col. 6, lines 56-59). Panescu et al. also teaches that a graphical representation of the device may be provided and that the representation may be used in combination with the fluoroscopic images of the position of the device (col. 6, lines 31-46). Further, Panescu et al. teaches that a wire-frame image of the device may be used (col. 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the configuration input scheme and visual representations of Panescu et al. with the system of Dumoulin et al. '165 in order to provide the operator with improved orientation of the device within the subject (see for motivation Panescu et al. at col. 5, lines 65-67 and col. 6, lines 6-12).

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianne M. Sullivan whose telephone number is 571-272-6084. The examiner can normally be reached on Monday through Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWJ JMS

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700